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| 10/689,469 | 10/20/2003 | Patrice Debregeas | 065691-0339 | 4165 |

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| EXAMINER | |
|---|---|
| BASQUILL, SEAN M | |

| ART UNIT | PAPER NUMBER |
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| 4161 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/689,469 | DEBREGEAS ET AL. | |
| | Examiner | Art Unit | |
| | Sean Basquill | 4161 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

Claims 1-12 stand REJECTED.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 4 recites the limitation "the pharmaceutically acceptable excipient" in Claim 1. There is insufficient antecedent basis for this limitation in the claim, because the amended Claim 1 no longer includes a pharmaceutically acceptable excipient.

2. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, given the claim language and specification paragraph 23 the examiner is uncertain as to the exact composition of the neutral core as claimed. Given the claim refers to a starch/sucrose core containing 20% starch and 80% sucrose, the phrase "coated by 80% by weight of starch" at least implies that the core itself must contain an additional starch solution coating prior to being coated with the plant containing layer. The remainder of the disclosure does little to clarify the examiner's confusion as to the core composition, as only paragraph 23 of the specification appears to refer to the composition of the neutral core. Claim 3 therefore fails to reasonably convey to one of skill in the art the metes and bounds of the claimed invention to provide notice of what would and would not constitute an infringing activity.

3. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claim 12 teaches granules comprising multiple layers, one or more of which comprise the mixture of PVP and plant extract, and alternating layers. It is unclear from the language of Claim 12(B) whether the invention comprises multiple layers containing plant extract, or layers of plant extract which alternate with layers containing no active ingredient. Previous descriptions of the "layer comprising pharmaceutically acceptable excipient" have also contained plant extract. Likewise, previous descriptions of layers

"compris[ing] PVP as a binder" have also contained the active plant extract in question. Claim 12 therefore fails to reasonably convey to one of skill in the art the metes and bounds of the claimed invention to provide notice of what would and would not constitute an infringing activity.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-12 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,949 (hereinafter "Menzi"), Allen R. Nissenson, et al, *Mannitol*, 131 WEST J MED. 277 (Oct. 1979), U.S. Patent 4,960,596 (hereinafter "Debregeas I"), U.S. Patent 6,030,621 (hereinafter "De Long"), and U.S. Patent 6,228,395 (hereinafter "Debregeas II") for the reasons set forth in the prior non-final and final rejections dated 8 March 2007 and 21 September 2007 respectively. Because the applicants did endeavor to modify the scope of their claims in an

attempt to claim around the rejections as presented by the previous examiner, the instant examiner will likewise attempt to explain why the amendments as presented fail to overcome the stated rejections, as well as why the aforementioned rejections stand in the instant application.

5. First, the examiner notes that the amendments to Claim 1, contrary to the intent expressed in the arguments filed 21 February 2008, **expands** the scope of the claims by removing as a claim element afforded patentable weight the phrase "pharmaceutically acceptable." The applicant's amendments have shifted the specified language into the claim preamble, which according to MPEP 2111.02, limits a claim only when "recit[ing] limitations of the claim, or . . . is 'necessary to give life, meaning, and vitality' to the claim." Such a determination is of course made on a case-by case basis considering the claim in question. When preamble language does not recite a claim limitation or provide life, meaning and vitality to the claim, it simply recites an intended use of the invention as claimed. Where, as here, the claim without granting the preamble patentable weight reasonably reads on "granules containing at least one plant substance comprising a single neutral core…with a layer containing the plant substance combined with PVP as a binder," the preamble language neither recites a claim limitation nor is 'necessary to give life, meaning, and vitality' to the claim" so far as "pharmaceutically acceptable," or the instant "pharmaceutical formulation" language is concerned. In the instant Claim 1, the phrase "pharmaceutical formulation" simply recites an intended use of the composition as claimed.

6. Likewise, considering the claim language as a whole, the addition of the term "single" before "neutral" is of little consequence given the examiner's interpretation of the term "a" in the prior claim to read upon a single core upon which the claimed layers were thereafter placed. The

amended Claim 1 resulted in the following claim language modification (instant and prior claim language presented for comparison):

a. "A pharmaceutical formulation in the form of granules. . . each comprising a single neutral core…" (instant claim);

b. "Granules . . . comprising a neutral core" (prior claim);

Both the original and currently amended claims read upon granules comprising at least one plant substance and PVP as a binder. The prior Claim 1 language specifying "**a** neutral core," claimed in the singular without further elaboration in the specification, permitted the examiner to conclude that each granule comprised one core; inclusion of the word "single" in this instance renders the phrase redundant. Likewise, the previous claim reasonably reads on requiring each granule be composed from a single neutral core upon which additional layers are thereafter placed. The examiner is unaware of any alternative interpretation of the prior claim language, but invites the applicants to clarify how their inclusion of the term "each" substantially modifies the previously presented Claim language if the examiner's interpretation varies from that which was intended.

7. Moving now to Applicant's arguments as presented in the Amendment and reply under 37 CFR 1.116 filed 21 February 2008, Menzi clearly describes the use of a neutral core in a composition which is pharmaceutically useable (C.2, L.8), which may be made from sugars, (C.2, L.11-12), as described in previous rejections, but also sugar alcohols. (C.2, L.14-15). Menzi does not specifically describe the use of mannitol as a sugar alcohol. However, despite not specifically reciting the use of mannitol, Menzi would clearly indicate to one of ordinary skill in the art at the time the invention was made that any sugar alcohol, as a known equivalent, could

serve the purpose served by isomaltol as described. (C.2, L.15). In addition, for the reasons outlined in Paragraph 7 above, the phrase describing "pharmaceutical formulation[s]" has been given little, if any, patentable weight owing to its role as an intended use of the claimed composition. Therefore, applicant's otherwise eloquent arguments presented in page 5, paragraph 3 of the Request for Continued Examination have been considered and found unpersuasive.

8. In light of the foregoing analysis of the impact of the amended claim language, the examiner contends that the amendments in this RCE have resulted in no change in the invention as claimed, and would have properly been finally rejected on the grounds and art of record in the next Office action had they been entered in the earlier application.

## *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
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/Ashwin Mehta/
Primary Examiner, Technology Center 1600